RESULTS

Personal exposures and area concentrations, ventilation measurements, and work practice observations for the study are reported below. The hospitals are identified by an arbitrary letter designation (see Table 3). Two of the hospitals had two sterilizers, and in some cases it was necessary for the sterilizers to have a unique identifier, so they have been arbitrarily numbered from 1 to 11. (Note: the letter and number designations are not related to expected effectiveness or any other specific factor.)

AIR SAMPLING

Two of the three types of air samples consisted of at least two different groups of samples. The charcoal tube samples were taken for a full shift and/or a short-term period. For the gas bags, some of the samples were taken for every load, and others were taken only occasionally. Certain values were computed from the infrared analyzer data to be compared with the other methods.

Comparing the time-weighted average results of short-term samples with different sampling periods can be misleading when the concentration is elevated for only a fraction of the sampling period. For example, referring to Figure 4, the time-weighted average for the 2-minute sampling period is much greater than for the 15-minute sampling period, even though the worker was exposed to the same quantity of EtO. This distortion can be rectified by working with the "exposure-dose" or concentration-time product (ppm-min). Mathematically, this is the area under the curve (i.e., the integral) of the instantaneous concentration; the quantity which is divided by the sampling time to yield the time-weighted average. The value of this measure is that when the bulk of an exposure may have occurred in a short period of time, as is shown in Figure 4, the same concentration time product would result as long as the exposure peak occurred within the sampling period. Therefore, in the situation illustrated in Figure 4, the time-weighted average concentration would differ greatly; but the computed exposure-dose would be the same.

Generally, all the data are lognormally distributed. Therefore, the logarithms of the values were used in all statistical analyses. However, the results have been transformed back to the original units (ppm or ppm-min) for presentation in the report.

Although in some cases the results seemed different depending on whether test loads or normal loads were processed, no formal statistical test showed a significant difference between test loads and normal loads. The SAS® t-test procedure (PROC T-TEST) was used on all the data separated by hospital, sterilizer, sampling site, day, and shift. None of the individual t-tests resulted in a probability of a greater absolute value of t under the null hypothesis (i.e., the 2-tailed significance probability) of less than 0.01.

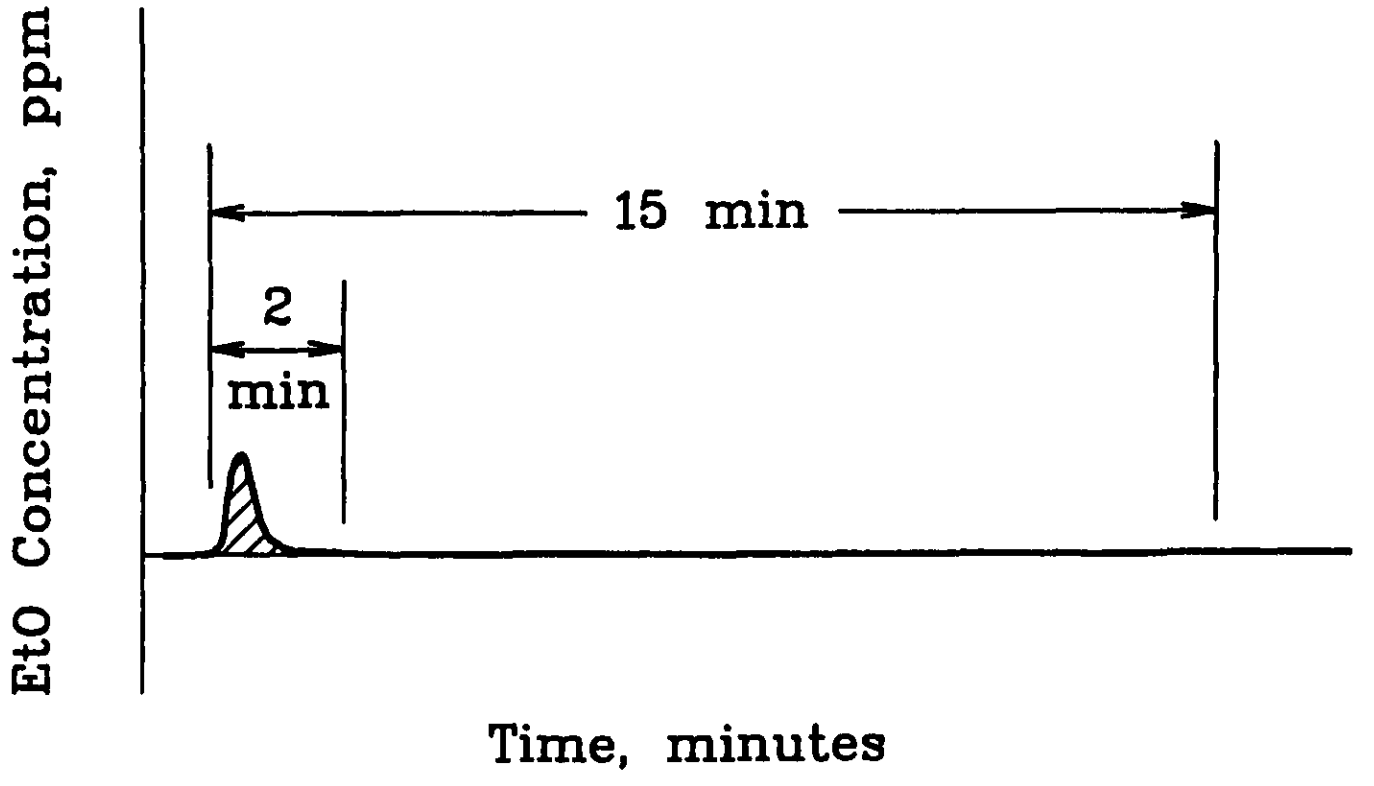

Figure 4. Two different sampling periods, each containing the same exposure peak, have different average concentrations but the same concentration-time product represented by the cross-hatched area.

Most of the values for Prob>|T| were greater than 0.1. Thus, all loads are considered together in the following comparisons unless otherwise noted.

Charcoal Tubes

For Hospital A, almost all the charcoal-tube sample results were indistinguishable from the results reported for the field blanks. These results are interpreted to represent no detectable EtO on the samples. In fact, almost all the charcoal tube results were near the limit of detection (LOD) of the analytical method. Table 5 lists the various LODs for the different surveys and the percentage of samples less than each LOD at each hospital.

Because of the number of samples below the limit of detection, complete data were not available for many of the hospitals. For some of the surveys, most of the results were reported as being less than a LOD which was higher than other "detected" samples at that hospital. Such values cannot provide meaningful results in parametric analyses. Thus, it was decided to use only values greater than the LOD because using an estimated value (e.g., 1/2 concentration corresponding to the LOD) based on the LOD for an unknown ("not detected") result could be misleading. This approach reduces the number of data points used in the analyses; in some cases, resulting in no data points at all for a hospital.

Full-Shift Results--
All full-shift time-weighted averages were less than 1 ppm. Most were less than 0.1 ppm; however, for Hospital I -- the hospital with the fewest controls -- all the full-shift results were greater than 0.1 ppm. The values are listed in Table A-1.

Figures 5 to 8 show the distribution of values for the detected full-shift charcoal tube samples. Separate figures are presented for the sterilizer operator, the other worker for which a personal sample was collected, the area in front of the sterilizer, and the other area sampled. In Figure 5, only Sterilizer 6 (Hospital I) routinely had values greater than the NIOSH Recommended Standard. The one detected sample for Sterilizer 3 was collected when the drain was not properly sealed, and it is not representative of the other values which were less than the analytical detection limits. Referring to Figure 6, Sterilizers 7 and 8 (Hospital F) and Sterilizers 10 and 11 (Hospital H) were located in sterilizer isolation rooms.

Short-Term Results--
Except for four samples in Hospital I, all the values for the operator exposure-dose were less than 20 ppm-min. A number of values for the short-term area concentration-time product in front of Sterilizers 6, 10, and 11 were greater than 50 ppm-min, the product of the 5 ppm ceiling limit and the maximum time period for exposures this high of 10 minutes recommended by NIOSH. This indicates the potential for overexposure if workers spent too much time on this area during this period of elevated concentration. Figures 9 and 10 show the distribution of values. Table A-2 lists all the short-term charcoal tube results.

Table 5. Charcoal tube samples below the limit of detection

Hospital	LOD µg	number of samples	percent of samples below LOD
A	0.36*	35	94
B	0.1	66	52
C	0.2	20	85
	0.4	24	54
	0.9	26	69
D	1.4	73	89
E	0.29	22	68
	0.33	19	53
	0.5	19	47
	1.2	1	0
F	0.1	96	6
G	0.1	78	3
H	0.2	21	5
	0.4	19	11
I	0.1	73	0

* based on field blanks

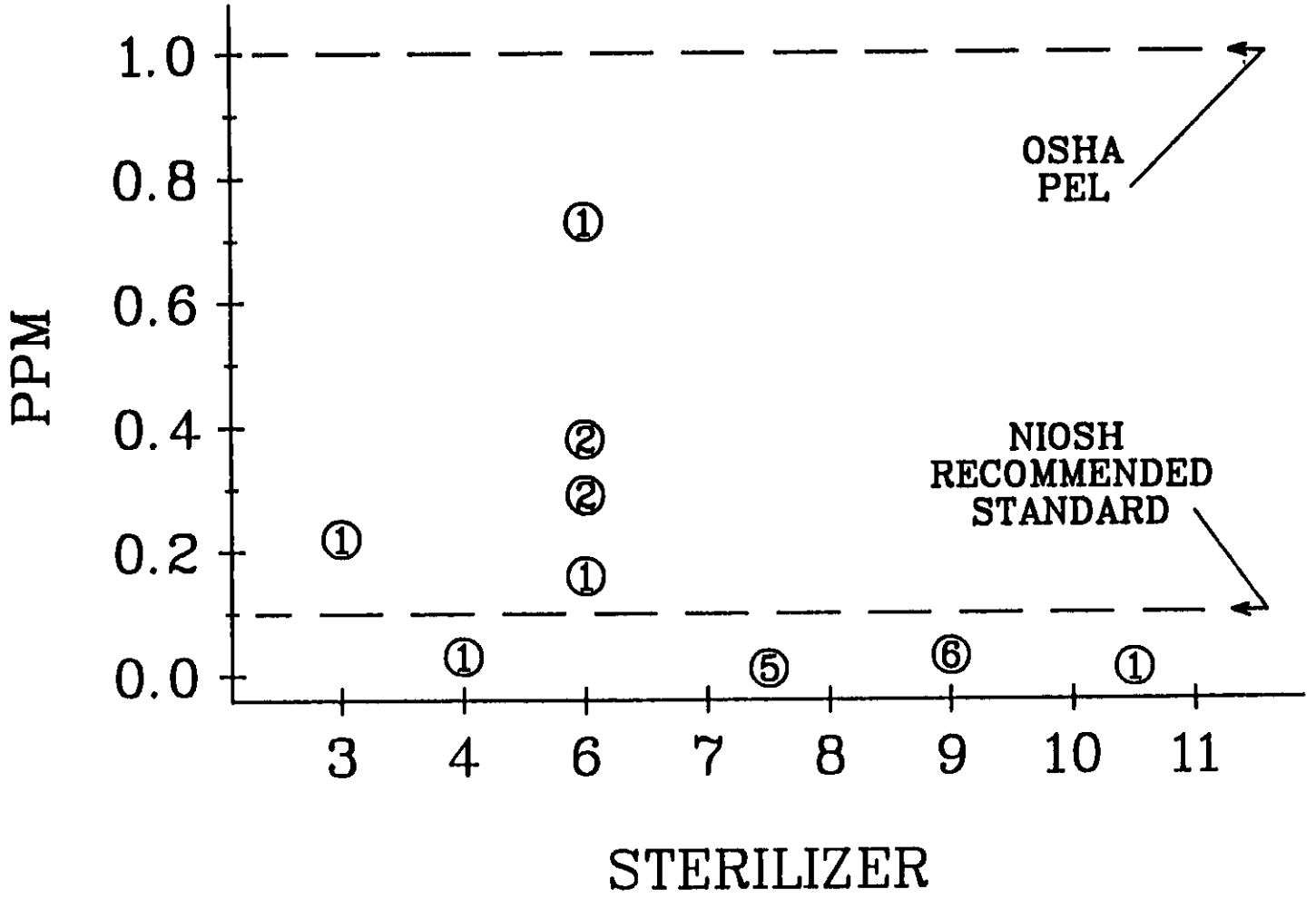

Figure 5. The number of samples with concentrations in the ppm range covered by the circle for the full-shift exposures for sterilizer operators, sampled with charcoal tubes, is shown for each hospital represented by sterilizer number. Note that Sterilizers 7 and 8 were in one hospital; Sterilizers 10 and 11 were in another hospital.

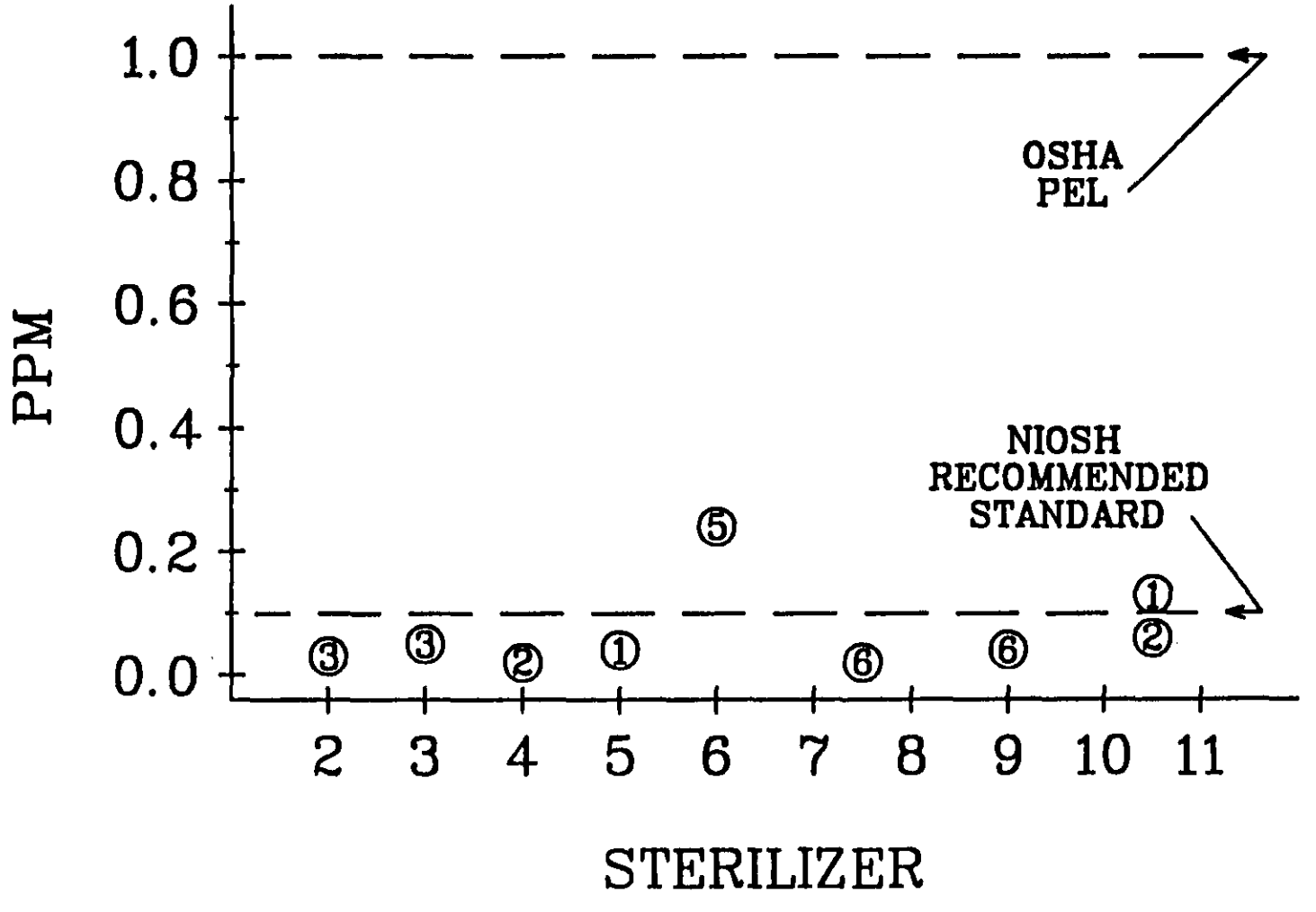

Figure 6. The number of samples with concentrations in the ppm range covered by the circle for the full-shift area concentrations in front of the sterilizers, sampled with charcoal tubes is shown for each sterilizer.

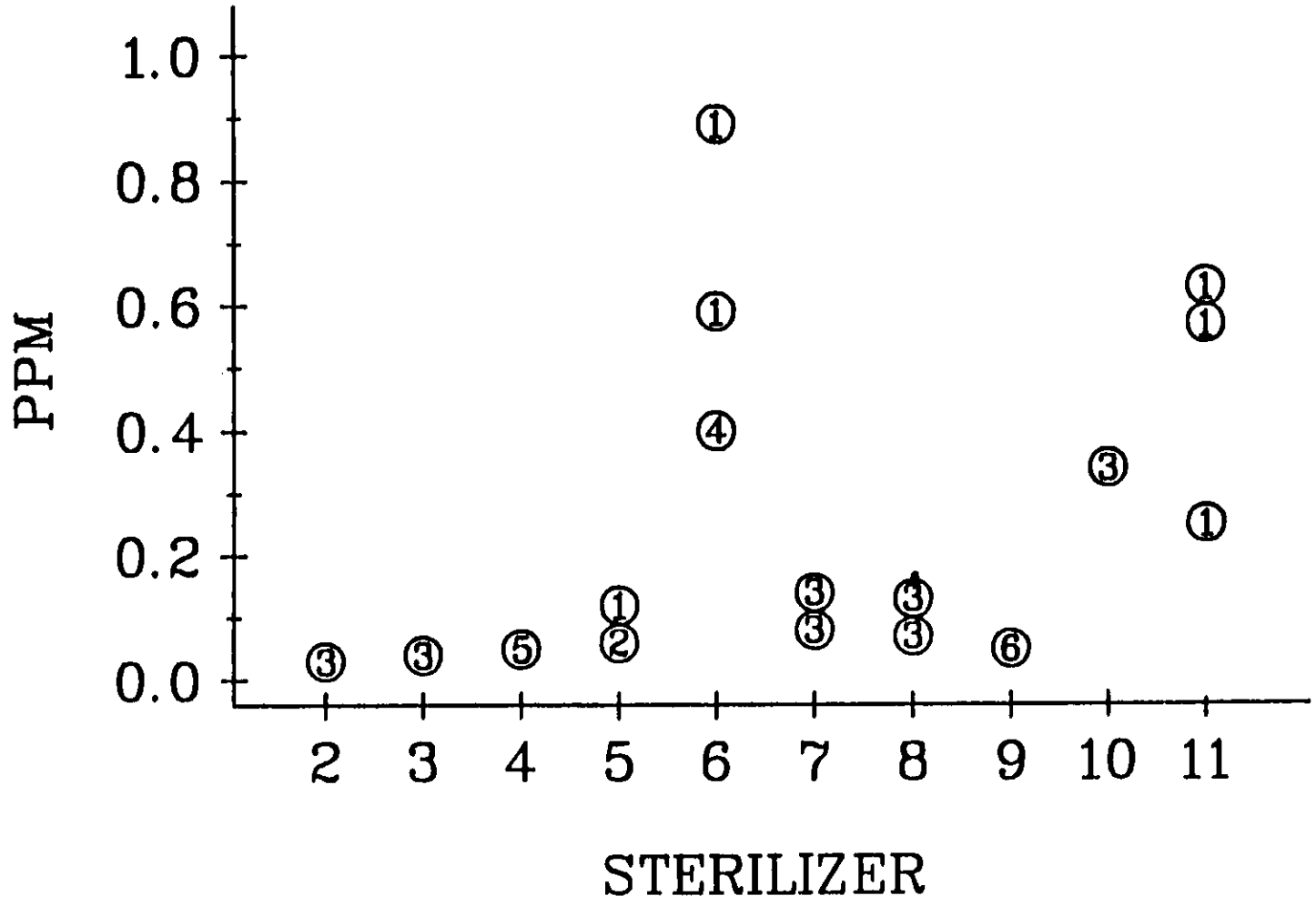

Figure 7. The number of samples with concentrations in the ppm range covered by the circle for the full-shift exposures of the other workers sampled with charcoal tubes is shown for each hospital represented by sterilizer number. Note that Sterilizers 7 and 8 were in one hospital; Sterilizers 10 and 11 were in another hospital.

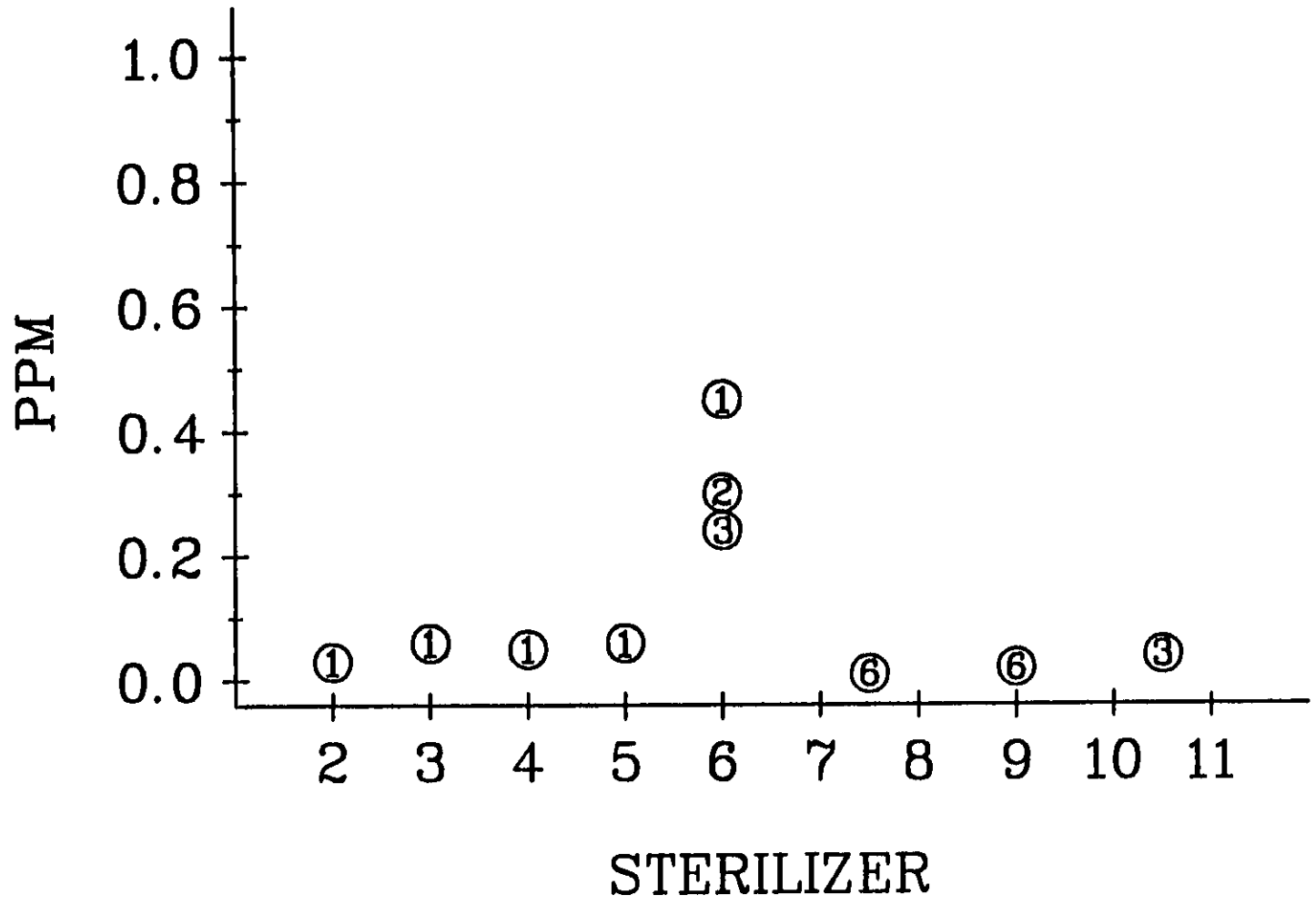

Figure 8. The number of samples with concentrations in the ppm range covered by the circle for the full-shift concentrations at the other area location sampled with charcoal tubes is shown in each hospital represented by sterilizer number. Note that Sterilizers 7 and 8 were in one hospital; Sterilizers 10 and 11 were in another hospital.

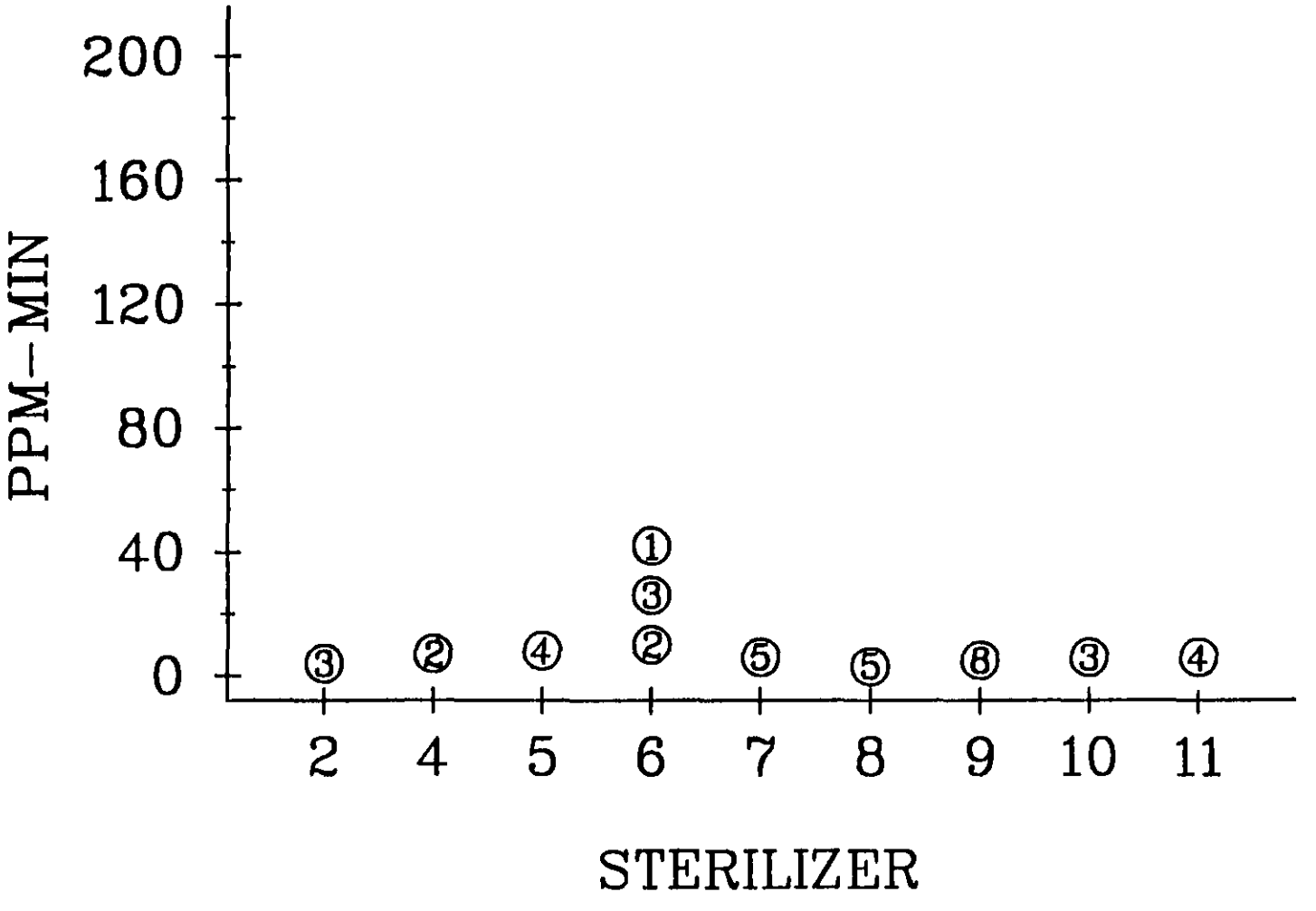

Figure 9. The number of samples with concentrations in the ppm-min range covered by the circle for the short-term exposures for sterilizer operators, sampled with charcoal tubes, is shown for each sterilizer.

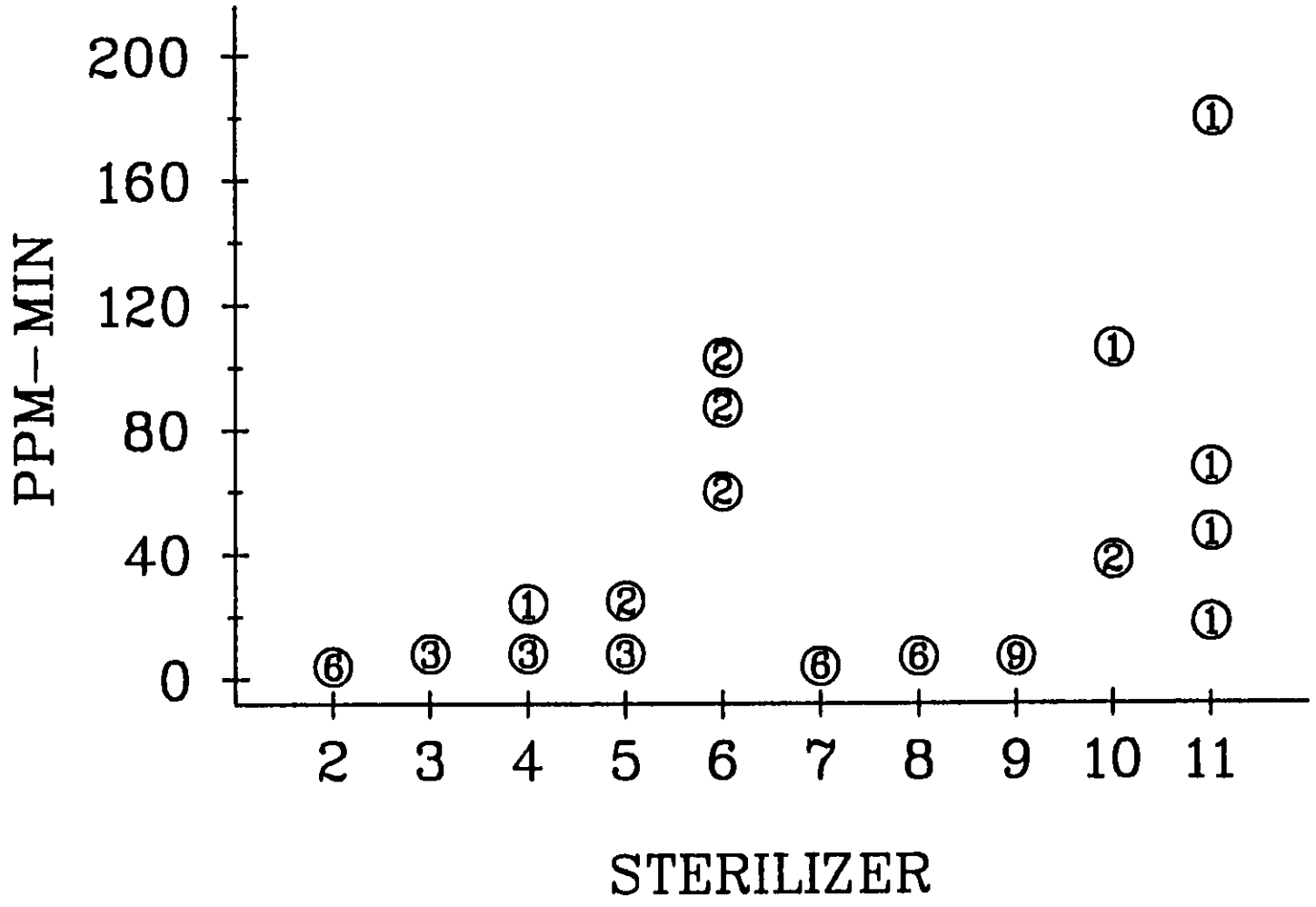

Figure 10. The number of samples with concentrations in the ppm-min range covered by the circle for the short-term area concentrations in front of the sterilizers, sampled with charcoal tubes, is shown for each sterilizer.

Gas Bags/Portable Gas Chromatograph

Other than the samples in Hospital A, only a few of the samples collected on gas bags were less than the LOD of the portable GC. Figures 11 and 12 show the distribution of values for the short-term gas bag samples for the sterilizer operators and the area in front of the sterilizers. All the operators' exposure doses were less than 20 ppm-min. Four sterilizers (4, 6, 10, and 11) had concentration-time products for the area in front of the sterilizers greater than 50 ppm-min. These results are similar, although not in complete agreement with the similar samples collected with charcoal tubes. All the gas bag/portable GC results are reported in Tables A-3 and A-4.

Figure 13 shows the distribution of values of chamber concentration collected just before the door was fully opened to remove the load. Except for Sterilizers 4, 5, and 9, for which a door-cracked period was not used, almost all the individual values are less than 300 ppm. For Sterilizers 1, 7, and 8, all values were less than 20 ppm -- Sterilizer 1 used in-chamber aeration; Sterilizers 7 and 8 used single-dose cartridges. All the results for the concentration in the sterilizer before the door was partially opened to start a door-cracked period (dc-ppm) and/or just before the door was fully opened to remove the load (do-ppm) are listed in Table A-5.

Table 6 lists the results of bag samples collected on a nonroutine basis. These samples were collected as the opportunity arose. Although these data are limited by the lack of replications, some of the individual samples seem especially interesting in their relationship to other observations. Personal and area samples for a cylinder change operation averaged 0.1 ppm at Hospital A, which had local exhaust ventilation above the supply cylinders. The EtO supply line connection to the cylinders at Hospital B had neither local exhaust ventilation nor a vent valve, and when the supply line was disconnected to change the cylinder, EtO sprayed out resulting in both a skin exposure and an area concentration of approximately 100 ppm.

At Hospital C, the short-term exposure to the operator while arranging the items in the aerator was 0.3 ppm and the corresponding concentration in the aerator before the door was fully opened was 1.8 ppm. Similarly, at Hospital I, the exposure to the operator while arranging items in the aerator was 0.5 ppm, and the concentration in the aerator before the door was fully opened averaged 1 ppm. A higher concentration (2.1 ppm) was measured in the aerator of Hospital G, but generally, the aerator did not seem to be a significant exposure source.

The sterilizer chamber retains EtO if not "aired-out." For Hospital G, the load was transferred without a door-cracked period and then the sterilizer door was closed. The concentration inside the chamber some time (a few hours) after the load transfer averaged over 200 ppm. At Hospital D, although a door-cracked period was not used prior to load transfer, the door was left partially open overnight. The chamber concentration prior to cleaning the interior of the sterilizer chamber the next morning averaged 0.56 ppm, and the exposure to the worker while cleaning the sterilizer chamber averaged 0.27 ppm.

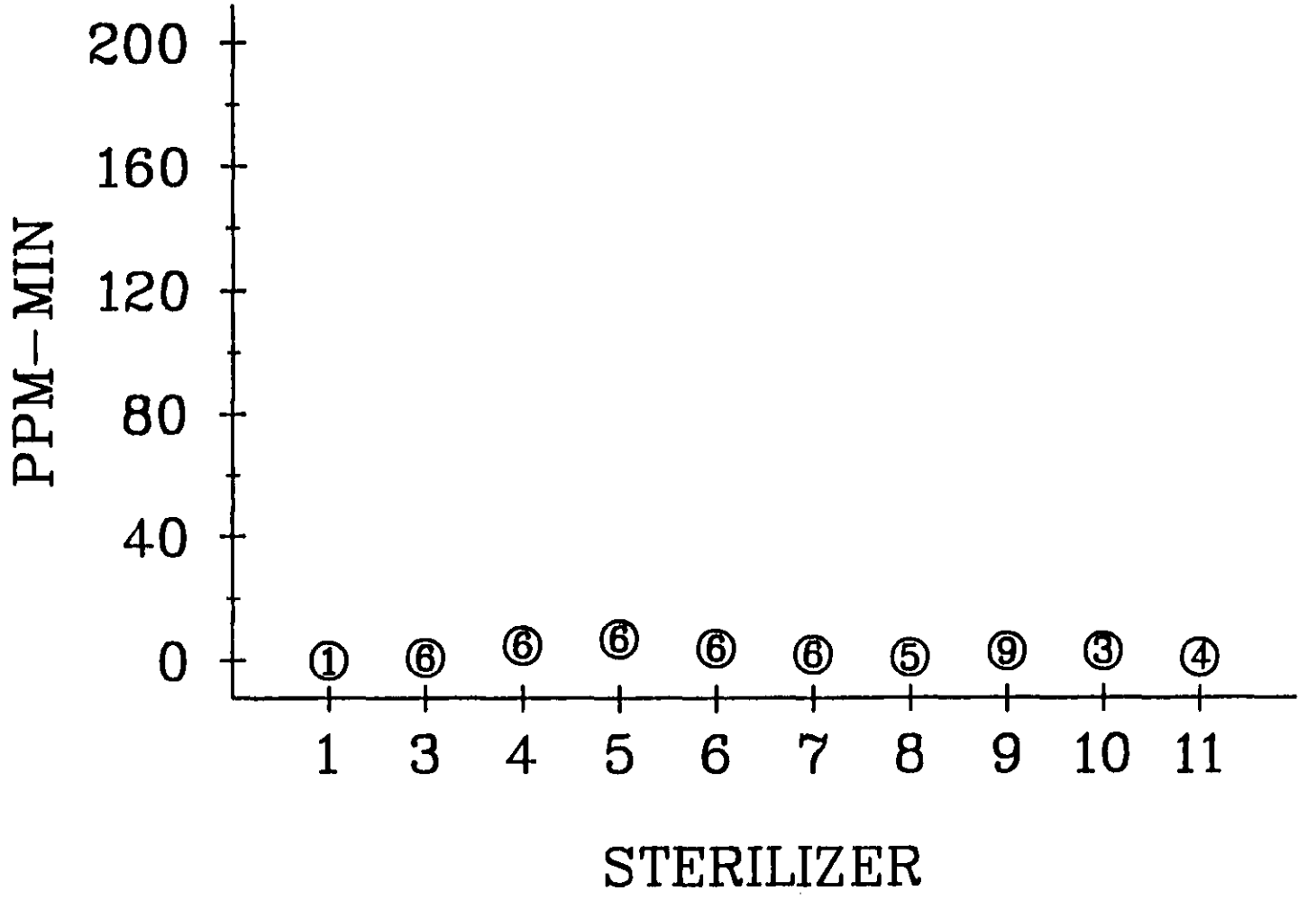

Figure 11. The number of samples with concentrations in the ppm-min range covered by the circle for the short-term exposures of the sterilizer operators during just the load transfer, determined by portable gas chromatograph analysis of gas bag samples, is shown for each sterilizer.

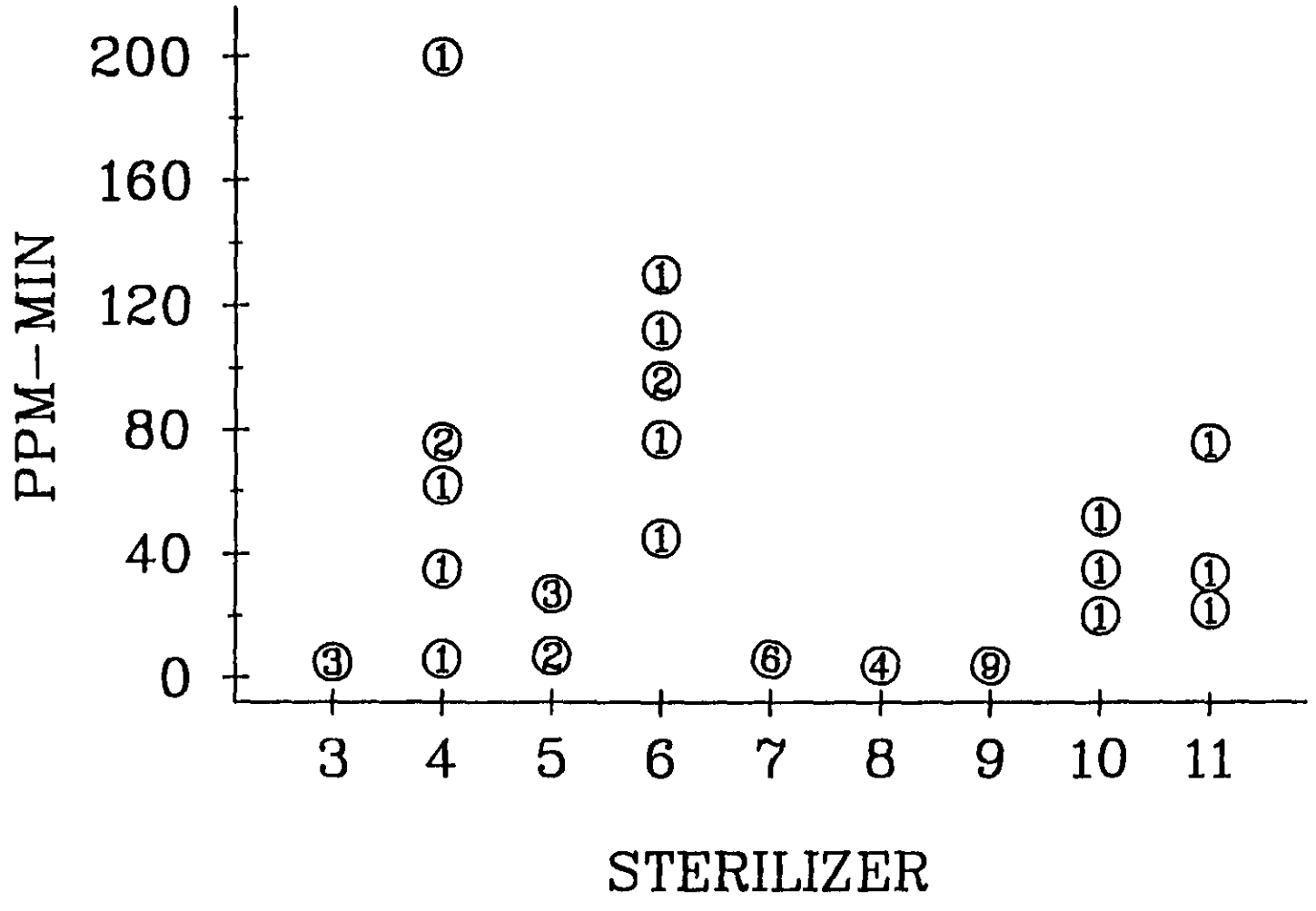

Figure 12. The number of samples with concentrations in the ppm-min range covered by the circle for the short-term area concentrations in front of the sterilizers determined by portable gas chromatograph analysis of gas bag samples is shown for each sterilizer.

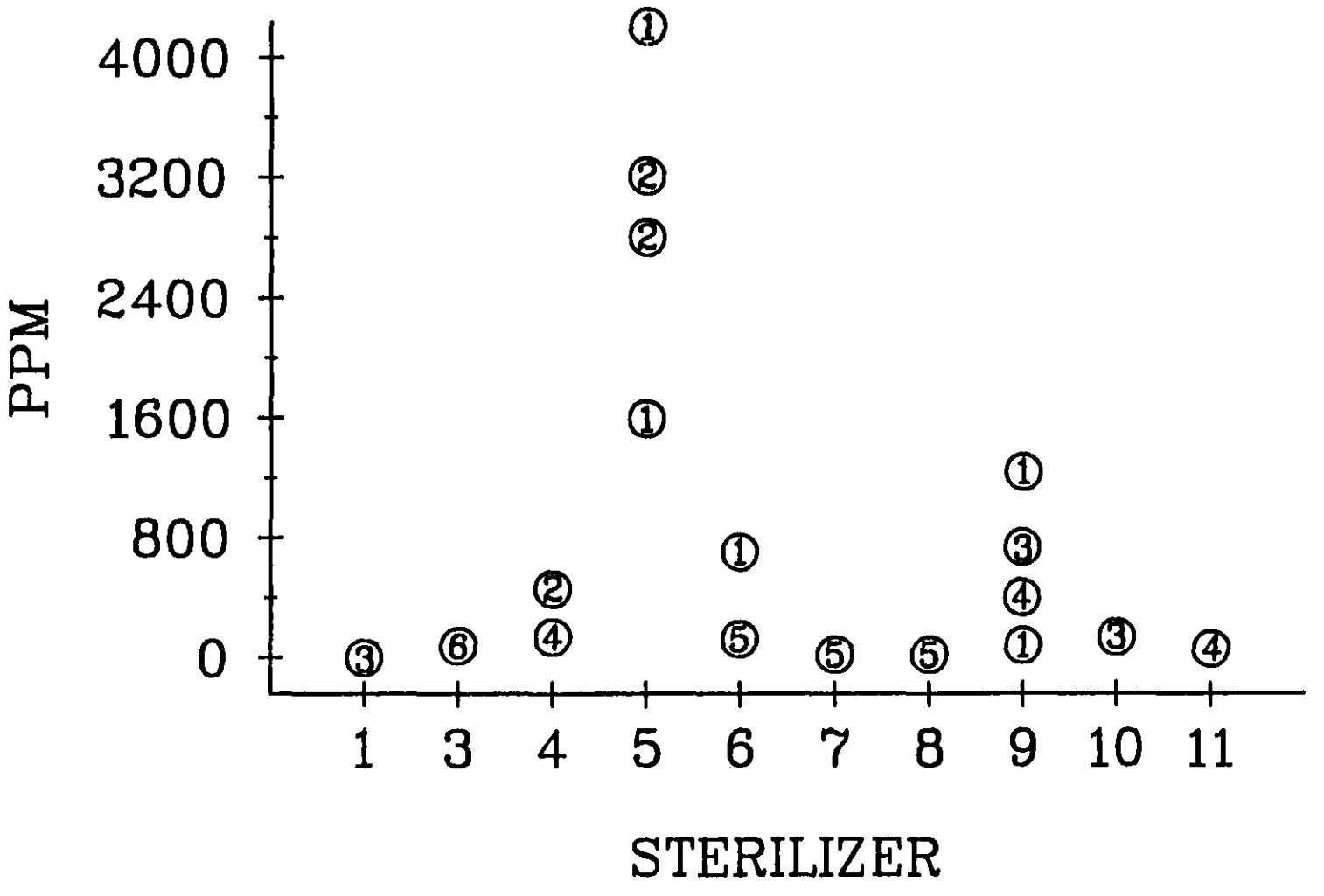

Figure 13. The number of samples with concentrations in the ppm range covered by the circle for the concentration in the sterilizer when the door was opened to remove the load, determined by portable gas chromatograph analysis of gas bag samples, is shown for each sterilizer.

Table 6. Results* of selected nonroutine gas bag samples.

Hospital	Description of Sample	ppm (#)**
A	Personal sample during cylinder change operation	0.1 (1)
	Area sample during cylinder change operation	0.1 (1)
B	Area sample during cylinder change operation	100. (1)
C	Operator arranging loads in aerator	0.3 (1)
	Inside aerator chamber	1.8 (1)
	Above load after sterilization	57. (2)
	Operator opening biological indicator pack	0.2 (1)
D	Operator cleaning sterilizer chamber	0.27 (3)
	Inside Sterilizer Chamber	0.56 (3)
G	Inside aerator chamber	2.1 (1)
	Inside Sterilizer Chamber	214. (2)
H	Worker performing maintenance	3.5 (1)
I	Operator arranging loads in aerator	0.5 (1)
	Inside aerator chamber	1.0 (2)
	In front of sterilizer during maintenance	13. (2)
	In front of sterilizer, not during purge or LT	0.30 (3)

* Geometric mean if more than one sample
** The number of samples is in parentheses

The newly sterilized load can be a source of EtO. The concentrations measured during the load transfer at Hospital C ranged from 7 ppm approximately 10 inches above the load to 106 ppm approximately 2 inches above the load. However, the exposure to the operator while opening the biological indicator pack was 0.2 ppm.

Sterilizer maintenance can also lead to EtO exposure. The exposure to a worker performing maintenance on the water-sealed vacuum pump of a sterilizer in Hospital H averaged 3.5 ppm for approximately 1 minute. At Hospital I, during maintenance on the EtO supply system in the mechanical access room, the concentration in front of the sterilizer averaged 13 ppm, and 0.3 ppm during a time when elevated concentrations were not expected.

Infrared Analyzer

Typical responses of the infrared (IR) analyzer with the probe placed at the area location in front of the sterilizer during the purge cycle and the load transfer are shown in Figure 14. This information is not available for Hospital H -- at this hospital the IR analyzer monitored the appearance of EtO in front of one sterilizer during the purge cycle and load transfer for the other sterilizer.

Although instantaneous values measured by the IR analyzer were not considered accurate due to drift and a slow response, computing the area under the curve averages out these deficiencies. The average ppm-min and ppm values thus obtained are reported in Table 7. All the values gleaned from the IR tracings are reported in Appendix A, Table A-6.

VENTILATION

Local Exhaust Ventilation

All but one of the hospitals (Hospital I) had local exhaust ventilation (LEV) above the door of the sterilizer. Some pertinent data about the LEV hoods is summarized in Table 8. In most cases, the velocity (ft/min) of the air flowing into the hoods was measured at the face of the opening. If not, this value has been calculated by dividing the volume flow rate by the area of the opening at the face of the hood. Some hoods were located above the control panel rather than immediately above the door. These were usually larger, extending out further from the front panel of the sterilizer. These values along with the volume flow rate (ft^3/min) are presented in the table.

General Ventilation

The volume flow rate for the room in which most of the sterilization operations were located varied considerably. Even when adjusted for the volume of the room (often referred to as room air changes per hour), the values are still highly variable. These values for both the clean room, mechanical access room, and/or isolation room are reported in Table 9.

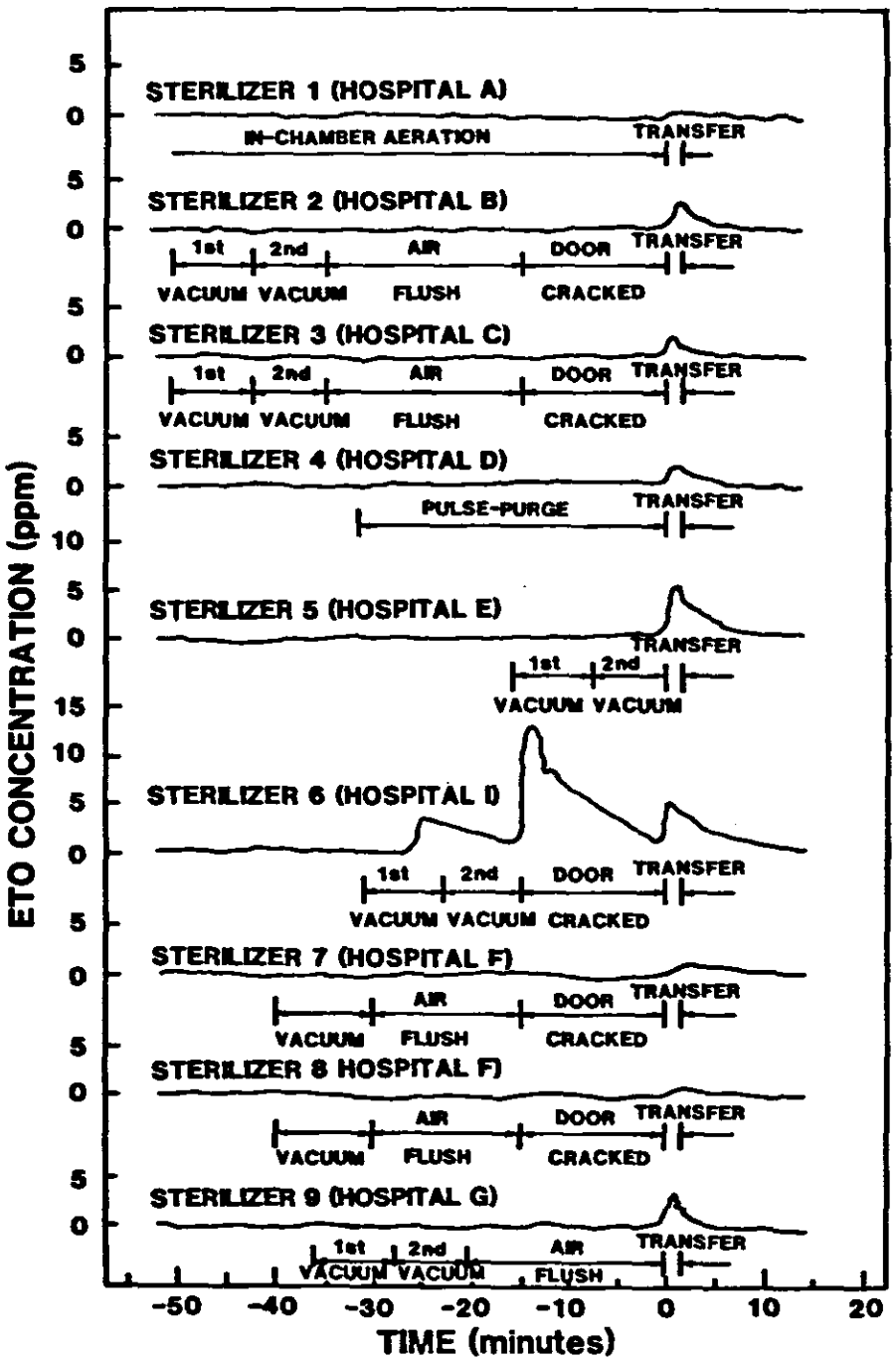

Figure 14. Representative infrared analyzer responses.

Table 7. Results from the infrared analyzer tracings.

Sterilizer	Number of Samples	Area under curve ppm-min	Average Concentration ppm
1	3	0.5	4.3
2	9	2.0	8.1
3	6	0.8	3.2
4	5	0.7	2.9
5	3	2.3	25.2
7	6	*	*
8	6	*	*
9	10	1.3	10.1
6	6	0.8	13.5

* Peak too small to be distinguished from base line fluctuations.

Table 8. Summary of local exhaust ventilation values.

Sterilizer	Distance above Sterilizer inches	Slot Area ft^2	Slot Velocity ft/min	Volume Flow Rate cfm
1	2	0.17	620	105
2	2	0.17	530	90
3	2	0.17	800	135
4	17	1.4	110	150
5	18	3.9	115	450
7	0	0.16	210	35
8	0	0.16	190	30
9	2	0.17	575	95
10	25	2.2	165	360
11	25	2.2	80	170

Table 9. Summary of general ventilation values.

Hospital	Room	Volume Flow Rate cfm	Room Volume ft^3	Flow rate to Room Vol. Ratio hr^{-1}
A	clean room	700	5400	8
A	mechanical access room	1250	590	127
B	clean room	1250	9100	8
B	mechanical access room	1000	2500	24
C	clean room	1750	12000	9
C	mechanical access room	120	1700	4
D	clean room	640	7100	5
D	mechanical access room	1000	1300	46
E	clean room	1100	5000	13
E	mechanical access room*	500	1600	19
E	mechanical access room**	2000	1600	75
F	isolation room	230	750	18
G	clean room	1900	9600	12
H	isolation room	530	760	42
I	clean room	1750	12000	9
I	mechanical access room	300	1700	11

* emergency exhaust off
** emergency exhaust on

Work Practices

Many factors affecting exposure are related to work practices. Those thought to be most significant in terms of exposure to EtO are compiled in Table 10. About half the hospitals used the door-cracked period. Likewise, about half of the hospitals -- although not the same ones -- used carts exclusively to load and unload the sterilizer. Generally less than 1 minute was required to transfer a load to an aerator. Only a few of the load transfers were completed by pushing or walking behind the load for an appreciable distance, and only one involved more than 10 seconds of close contact, as judged by the researchers while reviewing the videotapes.

Table 10. Summary of work practice parameters.

Hospital	operator	door-cracked period	mode of transfer	transfer time minutes*	motion of transfer	contact sec*
A	a	no**	cart/cart	**	pull	**
	b	no**	cart/cart	**	pull	**
B	c	yes	cart/basket	1.0	pull/swing	***
	d	yes	cart/basket	1.5	pull/swing	***
C	e	yes	cart/cart	0.5	push	4
	f	yes	cart/cart	0.4	pull	2
	g	yes	cart/basket	0.9	pull/swing	5
	h	yes	cart/cart	1.2	pull	5
D	i	no	basket/basket	0.9	pull/swing	6
	j	no	basket/basket	0.2	pull/swing	4
E	k	no	cart/cart	***	***	***
	l	no	cart/cart	1.1	push	5
	m	no	cart/cart	0.7	swing/push	6
	n	no	cart/cart	1.2	swing/push	7
F	p	yes	basket/basket	0.1	down****	3
	q	yes	basket/basket	0.1	down	3
	r	yes	basket/basket	0.1	down	3
	s	yes	basket/basket	0.1	down	5
	t	yes	basket/basket	0.1	down	6
G	u	no	basket/basket	0.4	swing	2
	v	no	basket/basket	0.3	swing/push	14
H	w	yes	basket/basket	0.3	swing	3
I	x	yes	cart/basket	0.4	pull	3
	y	yes	cart/cart	0.4	pull	1
	z	yes	cart/cart	0.3	pull	4

* geometric mean if more than one value

** no load transfer, aeration performed in the sterilizer

*** no value obtained

**** for one load, operator held basket on arm for a few seconds while opening aerator door

DISCUSSION OF CONTROLS

Because all of the sampled full-shift exposures were less than the 0.5 ppm, and most were less than 0.1 ppm, it should be expected that good controls were present in the hospitals surveyed. It is less obvious which controls were most responsible for the low exposures.

CYCLE MODIFICATIONS

EtO concentrations in the sterilizer during sterilization are greater than 200,000 ppm. Depending on the nature of the final chamber evacuation phase, concentrations in the chamber when the door is first opened may range from 40 to 4,000 ppm. Reducing the chamber concentration is an effective way to control the amount of EtO released to the room and the local concentration that the operator is exposed to during the load transfer. This reduction may be accomplished in various ways: deep-vacuum purges, a "pulse-purge" cycle, closed-door air flushes, and a door-cracked period. Although the effectiveness of each method varies, each of these methods is theoretically capable of reducing the chamber concentration by over 99 percent if performed long enough or often enough. Usually, a combination of these methods is used. Such is the case with "in-chamber aeration," which involves leaving the load in the sterilizer and subjecting it to a series of vacuum cycles and closed-door air flushes for the duration of the aeration period.

The concentration measured in the sterilizer just before the door is opened fully to transfer the load is indicative of the effectiveness of the evacuation cycles at reducing the quantity of EtO which could be released into the workplace. Table 11 shows that all but two of the sterilizers had average chamber concentrations less than 300 ppm. One of the sterilizers with a concentration less than 15 ppm featured in-chamber aeration. Another in this low group had a pulse-purge cycle. The others used a door-cracked period and, in some cases, also a closed-door air flush.

For the two sterilizers with the higher concentrations, the loads were pulled immediately after the end of the evacuation cycles without a 15-minute door-cracked period. One of these, which had an average chamber concentration of 360 ppm, had a 20-minute closed-door air flush period after the two deep vacuum cycles. The other, whose average chamber concentration was 2,800 ppm had no additional cycles other than two deep vacuum cycles.

Of the four sterilizers in the low group which used a combination of vacuum purges, air flush cycles, and a door-cracked period, three were measured to have chamber concentrations of less than 100 ppm when the door was opened to transfer the load. (There were no chamber concentrations measurements for the fourth sterilizer.)

Table 11. Comparison of the operator's short-term exposure-dose to the chamber concentration when the door is opened to remove the load.

Sterilizer	Door-open concentration* ppm	Operator short-term exposure-dose* ppm-min
8	6	0.32
1**	11	0.18**
7	17	0.72***
11	32	0.75
3	98	0.57
10	130	1.91
4	270	2.93
6	280	3.31
9	360	1.7****
5	2800	5.43

* Geometric mean if more than one sample

** In-chamber aeration used for all sampled loads.

*** Includes value involving poor work practices.

**** Relatively strong air current flowed from the ceiling to the floor in front of the sterilizer.

Table 11 shows that the rank order of the operator short-term exposure is almost identical to the rank order of the chamber concentration when the door was opened to transfer the load. The values for one of the primary exceptions (Hospital F, Sterilizer 7) were skewed by one run characterized by almost no detectable EtO in the chamber when the door was opened and poor work practices during the load transfer. Recalculating the averages for this sterilizer without this run lowers the operator exposure value to 0.47 ppm-min and increases the chamber concentration value to 34 ppm, bringing it more in line with the other sterilizers at the top of the list. For the other exception (Hospital G), air flowed down through the area in front of the sterilizer, resulting in low operator exposures and area concentrations in front of the sterilizer despite the relatively high chamber concentrations. (This latter situation is discussed in the door ventilation section.)

Deep-Vacuum Purges

Of all the mentioned individual techniques, deep vacuum purges are among the most effective. The chamber concentration is reduced by first removing most of the EtO from the chamber (typically down to a gauge pressure of -0.9 atm). The reduction of concentration occurs when the reduced quantity of EtO is diluted by allowing clean air to flow into the chamber, replacing that which was evacuated.

The typical implementation of this technique is to draw one or two deep vacuums at the end of sterilization. Theoretical calculations (based on the ideal gas law assuming an empty chamber) predict, and survey results confirm, that evacuating the chamber to approximately 0.1 atmospheres (absolute pressure) and returning to atmospheric pressure would reduce the chamber concentration by approximately 90 percent for each vacuum cycle. The one hospital (E) for which the load was transferred to an aerator immediately following two vacuum purges had an average chamber concentration of approximately 2,800 ppm when the door was opened to transfer the load, a total reduction of 99 percent from the estimated chamber concentration during sterilization.

Pulse-Purge Cycle

Because the concentration reduction due to a vacuum purge depends only on the pressures (assuming that chamber temperature is held constant), not on time; pulse-purge cycles -- a series of many (usually shallower) vacuum purges -- are theoretically more effective, achieving a concentration of only a few parts per million before the end of 15 cycles. Survey results indicate that overall, the pulse-purge cycle achieved a 99.9 percent reduction after 30 cycles; however, the end-of-cycle concentrations (approximately 300 ppm) were not as low as predicted from ideal gas law calculations.

Closed-door Air Flush Period

The air flush is like a deep vacuum purge, except that the filtered air inlet is kept open so that air flows through the chamber. The effectiveness depends on the flow rate relative to the chamber size, the mixing of the flushing air with the chamber contents, and the duration. With all these variables, this

process is also difficult to model accurately. In one hospital (C), the addition of a 20-minute closed-door air flush period before the door was opened reduces the chamber concentration by over 80 percent from approximately 540 ppm to 80 ppm. At another hospital (G) which removed the load immediately after a 20-minute air flush (preceded by two deep vacuum purges) chamber concentrations averaged approximately 360 ppm. As it is not known what the chamber concentration was at the start of the air flush, the actual percent reduction cannot be calculated. Assuming a 90 percent reduction for each of the vacuum purges indicates that the air flush period reduced the chamber concentration an additional 65 percent.

Door-Cracked Period

The door-cracked period relies solely on diffusion and airflow driven by convection of air from the chamber to reduce the chamber concentration. This depends on the temperature of the air in the chamber, the amount the door is cracked, the duration, and to some extent on the presence of ventilation above the sterilizer door. Survey results have shown that a door-cracked period reduces the chamber concentrations by approximately 64 to 97 percent for all loads. The hospitals which used only a door-cracked period following two vacuum purges had chamber concentrations for the test loads ranging from 32 to 275 ppm.

With few exceptions, low operator exposures during the load transfer were coincident with low concentrations in the chamber when the door was opened to transfer the load, and sterilizers for which a door-cracked period was used had lower average chamber concentrations. All sterilizers for which a door-cracked period was used, except for Sterilizer 2 (for which chamber concentration data was not obtained), had average chamber concentrations less than 200 ppm. The reduction of chamber concentration during the door-cracked period ranged from 74 to 99 percent. (This includes sterilizers which had other cycle modifications.) In this procedure, the door should not be opened beyond the distance which the local exhaust ventilation above the door can capture air rising from the sterilizer -- this implies that this ventilation should be installed. A 15-minute door-cracked period is adequate; on the few occasions that the door was cracked for 20 to 30 minutes, the chamber concentration was not reduced significantly further. Workers should be kept away from the area in front of the sterilizer during this period.

In-Chamber Aeration

The exposure control advantages of having aeration take place in the sterilizer instead of having to transfer the load to an aerator should be obvious in terms of not only the lowest possible concentration of EtO in the chamber when the door is opened but also the lowest quantity of EtO residual "on" the items when the load is removed from the sterilizer. Survey data confirms that this technique results in essentially no detectable exposure to EtO. The one hospital surveyed which used this technique had exposures and area concentrations indistinguishable from the field blanks. Even the gas bag samples analyzed on the portable GC were not detectable at the standard calibration level used in the other surveys. Thus, even short-term exposures

(for approximately a minute) to remove the load from the sterilizer were less than 0.2 ppm.

STERILIZER DOOR

Any meaningful mathematical comparison of sterilizer door ventilation with exposure is complicated by not knowing the quantity of EtO which would reach the sampling location if there were no LEV. However, with the exception of the load in Hospital F during which undesirable work practices were used, the sterilizers with the highest operator's short-term exposures were the ones using the door-cracked period with no ventilation or the hospitals which took the load out of the sterilizer immediately and had a local exhaust hood far above (18 to 20 inches) to top of the sterilizer door. Similarly, the data show that the three highest operators' long-term exposures were for the three sterilizers which either had no ventilation above the door or a hood approximately 2 feet (rather than a few inches) above the door.

The size of the hood and the required flow rate depend on the location of the hood. When the sterilizer door is first opened, the air is hot (100 to 130°F), and it rises because it is less dense than the surrounding (cooler) air. The vertical velocity may be as high as 100 ft/min close to the control panel. As it rises, the flow entrains more air, and the ventilation hood needs to exhaust at least as much air as is rising up to it or some air (containing EtO) will not be captured. As more air is entrained, the plume of rising air widens and the distance out from the face of the sterilizer that air must be captured increases.

Referring to Figure 15, the plume of air rising from the sterilizer door, partially opened to a distance, d, would be expected to thicken by approximately one-third the distance, h, from the top of the door to the edge of the hood. If the hood is close to the top of the door, the hood need not be large. However, if the hood does not cover the plume of air, the flow rate should be sufficient to generate a capture velocity at the outer margin of the plume so that all of the air rising from the sterilizer door opening is redirected into the hood. As the door is opened further, capturing all the air becomes more difficult.

For a slot hood located no more than 3 inches above the door, the volumetric flow rate should be:

$$Q = 280(LD)$$

where: Q is the volumetric flow rate, cfm, of exhausted air,
L is the length, ft, of the slot,
and D is a distance (d + h/3), ft, out in front of the sterilizer.

It is not necessary that the hood extend out from the front panel as is shown in Figure 16. As long as the above ventilation criteria are met and the door is opened approximately 2 inches, all EtO escaping from the sterilizer during the door-cracked period should be captured.

If the hood is located more than 3 inches above the sterilizer door, it should extend as far as the buoyant plume of air. Functioning as a recovery hood, a

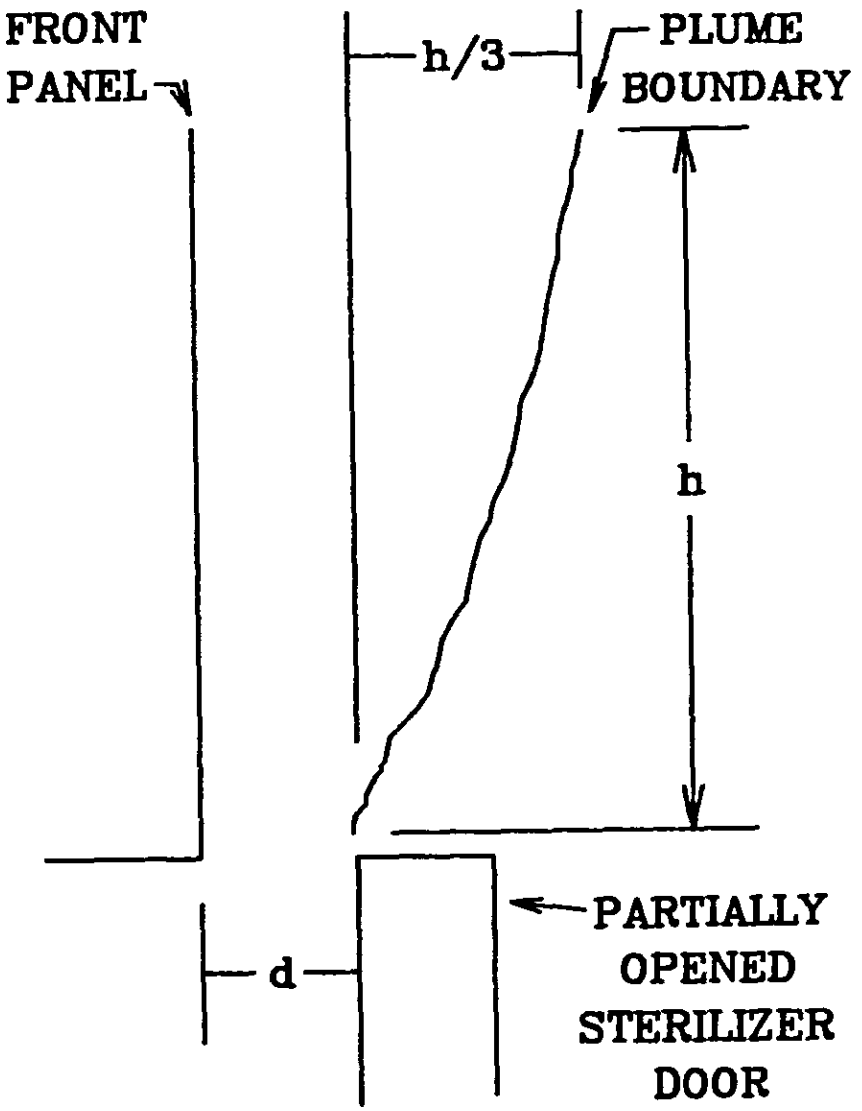

Figure 15. A plume of hot air escaping from a partially opened sterilizer door will spread out from the front panel about one-third the distance it has risen.

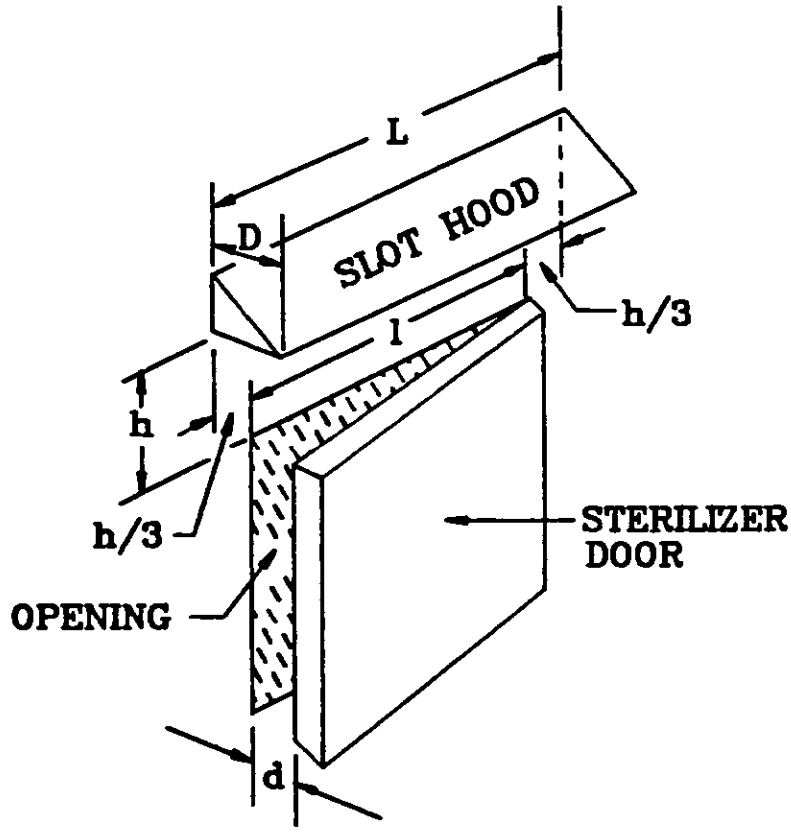

Figure 16. A slot hood placed no more than 3 inches above the sterilizer door can be used to capture the EtO escaping from the chamber during the door-cracked period. (See text for a discussion of the appropriate values for the variables.)

canopy hood (shown in Figure 17) needs to develop a volumetric flow rate somewhat longer than the plume of air rising into it. Therefore, the flow rate of air exhausted should be:

$$Q = 100(LW)$$

where: Q is the volumetric flow rate, cfm, of air exhausted,
L is the length, ft, of the hood,
and W is the width, ft, of the hood.

For a canopy hood, the width, W, should be the distance, d, that the door will be opened (i.e., 2 inches) plus the amount the plume will spread in front of the sterilizer:

$$W = d + h/3$$

In both cases, the length, L, of the hood should be the width, l, of the door plus twice the amount the plume will spread on each side of the door:

$$L = l + 2(h/3)$$

Based on observations during the surveys, opening the door 2 inches is sufficient to yield an adequate reduction of the chamber concentration during the 15-minute door-cracked period. Comparing the two different configurations for a typical case of a sterilizer with a door 2 feet wide, the exhaust required for the slot (approximately 2 inches above the door) would be 130 cfm. For a hood above the top of the control panel (approximately 24 inches above the door), 280 cfm would be required. These results are consistent with the values measured during this study.

Local ventilation above the door is most effective only in controlling the EtO released during a door-cracked period. However, due to the limited distance that the capture zone of a typical exhaust hood extends out from a sterilizer, this method is less effective during the load transfer. Moreover, the action of pulling the load from the sterilizer acts like a piston, drawing much of the air in the chamber up to 4 feet away from the sterilizer. The movement of the operator performing the load transfer and the prevailing air currents in the room add to the mixing of the chamber emissions to the air in front of the sterilizer and aerator and to the dispersion of EtO throughout the room. Exhaust ventilation which captures air up to only a few inches in front of the sterilizer has little effect in this situation.

One airflow pattern which was effective in the region beyond a few inches from the face of the sterilizer was a supply air inlet which created an air current moving down through the region in front of the sterilizer, moving much of the EtO-contaminated air out of the region and showering the operator with relatively clean air. The hospital in which this was found had one of the best (percent) ratios of average short-term sterilizer area concentration relative to the chamber concentration when the door was opened to transfer the load. The capture of air in front of the sterilizer appeared to not be as good at this hospital, but the overall control of EtO emissions was. During the one run when a deflector was added to disrupt the downflow air pattern and improve the capture distance of the local exhaust ventilation above the